

## WO9737035

Publication Title:

WHOLE BLOOD ANALYSIS OF PROSTATE SPECIFIC ANTIGEN SPOTTED  
ON A SOLID SUPPORT

Abstract:

Abstract of WO9737035

The present invention provides for the measurement of prostate specific antigen (PSA) from extracts of blood dried on a suitable solid support. PSA in solid support dried blood is stable for more than 100 days at room temperature. The procedure of the present invention can reliably distinguish normal from elevated levels of PSA and that facilitates screening and monitoring to detect disease in large scale mail-in programs to centralized laboratories.

Data supplied from the esp@cenet database - Worldwide

Courtesy of <http://v3.espacenet.com>

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : C12Q 1/00, G01N 33/53, 33/567	A1	(11) International Publication Number: WO 97/37035	(43) International Publication Date: 9 October 1997 (09.10.97)
---	----	---	---

(21) International Application Number: PCT/US97/05368  
(22) International Filing Date: 25 March 1997 (25.03.97)

(30) Priority Data:  
08/626,641 2 April 1996 (02.04.96) US

(71) Applicant: DIAGNOSTIC SYSTEMS LABORATORIES, INC. [US/US]; 445 Medical Center Boulevard, Webster, TX 77498-4217 (US).

(72) Inventor: SAVIANI, Gopal, V.; 445 Medical Center Boulevard, Webster, TX 77596-4217 (US).

(74) Agents: TURLEY, Patrick Joseph, Baker & Botts, L.L.P., 910 Louisiana, Houston, TX 77002 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, GR, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: WHOLE BLOOD ANALYSIS OF PROSTATE SPECIFIC ANTIGEN SPOTTED ON A SOLID SUPPORT

(57) Abstract

The present invention provides for the measurement of prostate specific antigen (PSA) from extracts of blood dried on a suitable solid support. PSA in solid support dried blood is stable for more than 100 days at room temperature. The procedure of the present invention can reliably distinguish normal from elevated level of PSA and that facilitates screening and monitoring to detect disease in large scale mass-in programs to diagnosed laboratories.

BEST AVAILABLE COPY

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TE	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GM	Guinea	ME	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

**BEST AVAILABLE COPY**

## WHOLE BLOOD ANALYSIS OF PROSTATE SPECIFIC ANTIGEN SPOTTED ON A SOLID SUPPORT

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to screening or testing for prostate specific antigen (PSA). More specifically, the present invention relates to a method for screening for PSA from whole blood spotted on a solid support. Additionally, the present invention relates to a test kit for screening or testing for PSA using the solid support.

#### 2. Description of the Prior Art

Prostate adenocarcinoma accounts for the majority of malignancies in males over the age of 65. Yearly screening for prostate cancer is recommended after the age of 45. There has been considerable effort toward identifying suitable prostate cancer markers to assist in screening and diagnosing this disease.

PSA is recognized as the most sensitive marker of prostate adenocarcinoma (Brawer MK. *Cancer* 1993; 71 (suppl):899-905; Oesterling JE. *J Urol* 1991; 145:907-23). PSA is also recognized as a proven screening vehicle (Gann PH, *et al.* *J Amer Med Assoc* 1995; 273:289-94.; Catalona WJ, *et al.* *J Urol* 1994; 151:1283-90). It is the most sensitive front line test for identifying prostate gland-contained, and hence presumably curable, cancer. PSA is also useful in detecting clinically significant tumors as opposed to latent, indolent microcarcinoma. For example, PSA is also superior to the conventional office practice of digital rectal examination (DRE). For example, Labrie *et al.* (*Clin Invest Med* 1993; 16: 425-39) showed that 97% of cancers detected at annual follow-up by DRE plus PSA testing were PSA-positive. Thus, only a minimal benefit accrues from including DRE in the medical evaluation.

Prostate specific antigen has also been used to detect the onset of puberty in children between ages 8 and 25 years (Vieira J.G.H., *et al.* *J Clin Endocrinol Metab* 1994;78:1185-1187). Since PSA is an androgen-dependent protein and its expression is up-regulated by androgenic steroid hormones, women with hyperandrogenic syndromes may also have elevated PSA in their serum. Additionally, PSA has now been found in the serum and extracts from breast tumors (Diamandis E.P., Yu H. *J Clin Endocrinol Metab* 1995;80:1515-1517), indicating that it has utility in breast cancer screening and monitoring.

Currently, PSA is tested by first collecting a blood specimen via venipuncture phlebotomy. This usually necessitates that the individual to be tested make a physician office or hospital visit. The blood so collected is usually processed for shipment to a suitable clinical

SUBSTITUTE SHEET (RULE 26)

BEST AVAILABLE COPY